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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,217

10/19/2005

Randolf Von Oepen

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11/03/2006

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/523,217

Applicant(s)

VON OEPEN ET AL.

Examiner

Kathleen Sonnett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-70 is/are pending in the application.
- 4a) Of the above claim(s) 58-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-57 is/are rejected.
- 7) ☒ Claim(s) 36-57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/31/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, newly renumbered claim(s) 36-57, drawn to an apparatus comprising a bar having a bore or eyelet extending laterally there through and a filament disposed through the bore or eyelet.

Group II, newly renumbered claim(s) 58-70, drawn to an apparatus comprising a tubular body or delivery sheath and a wire having a sharpened tip at the distal end and deployable from the tubular body or delivery sheath.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I invention is a bar having a bore with a filament disposed through the bore which is not present in Group II. The special technical feature of the group II invention is the specific claimed structure of a tubular body with a wire having a sharpened tip that is deployable from the tubular body.

During a telephone conversation with Mr. Nicola Pisano on 9/19/2006 a provisional election was made without traverse to prosecute the invention of Group I, newly renumbered claims 36-57 (originally numbered 1-22). Affirmation of this election must be made by applicant in replying to this Office action. Claims 58-70 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).
2. Misnumbered claims 1-35 presented in the amendment filed on 1/31/2006 that replace canceled original claims 1-35 also filed 1/31/2006 have been renumbered 36-70.
3. **Newly renumbered Claim 47** is objected to because of the following informalities: redundant language. Claim 47 includes the phrase "further comprising an eyelet coupled to the bar". This phrase appears in claim 45, from which claim 47 depends and it appears to the examiner that it has been accidentally included in claim 47. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 36-40, 44, 50-51, and 54-56** are rejected under 35 U.S.C. 102(b) as being anticipated by Kim (U.S. 5,810,884). Kim discloses an apparatus for facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising a bar having a proximal and distal ends and a first bore extending laterally therethrough, and a filament disposed through the first bore, wherein the bar is configured to apply a compressive force upon

a distal lateral surface of a vessel (fig. 2a and 15). Regarding claim 50, the bore may instead be a first eyelet coupled to the bar (see fig. 9a-b).

6. Regarding claims 37 and 54, the apparatus further includes a delivery sheath having a proximal and distal end, a lumen therebetween and a sharpened tip at the distal end. The lumen is configured to contain the filament and bar (see fig. 10-13).

7. Regarding claims 38 and 55, the apparatus includes a push rod disposed in the lumen of the delivery sheath proximal bar (270).

8. Regarding claim 39, see figs. 2a and 9a.

9. Regarding claims 40 and 56, the rod (buttressing support member) may be biodegradable (col. 13, ll. 29-33).

10. Regarding claims 44 and 51, the hole and eyelet are in the central region of the bar (see fig. 2a and 9b).

11. **Claims 50-51 and 57** are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (U.S. 5,411,520). Nash et al. discloses an apparatus for facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising a bar having proximal and distal ends and a first eyelet to the bar (fig. 12), a filament disposed through the eyelet, wherein the bar is configured to apply a compressive force upon a distal lateral surface of a vessel.

12. Regarding claim 57, Nash discloses a tensioning device (fig. 13, 14, and 26) configured to hold the filament in a tensioned state.

13. **Claims 36 and 48** are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (U.S. 5,546,178). Kensey et al. disclose an apparatus for facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising a bar having a proximal and distal ends and a first bore extending laterally therethrough, and a filament

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disposed through the first bore, wherein the bar is configured to apply a compressive force upon a distal lateral surface of a vessel (fig. 1 and 8). Regarding claim 48, the device further comprises a second bore extending laterally through the bar, wherein the filament is disposed between both the first and the second bore.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. **Claims 41-43 and 57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Nash et al. Kim discloses the invention substantially as stated above but fails to disclose a tensioning device configured to hold the filament in a tensioned stated.

16. However, Nash et al. discloses that it is old and well known in the art to include a tensioning device in devices used to facilitate the sealing of a puncture. Nash et al. discloses that such a tensioning device is necessary in order to maintain appropriate tension of the filament while the delivery sheath is removed (col. 14, ll. 29-35). The tensioning device is shown in figs. 13, 14, and 26. It comprises an upright (142) having upper and lower ends, a plurality of legs attached to the lower end, and a grip affixed to the upper end. The legs are being considered the two pieces defined by the slit (142D) at the lower end of (142) and the grip is the portion attached to the upper end of (142) that also has a slit (142D). Regarding claim 43, the grip comprises a V-shaped groove formed in the tensioning device formed in the flexible material of the tensioning device, which is being considered equivalent to an elastomeric material. Therefore, it would have been obvious to one of ordinary skill in the art to modify the

device of Kim to include a tensioning device as made obvious by Nash et al. in order to gain the advantage of maintaining appropriate tension of the filament while removing the delivery sheath.

17. **Claim 49** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. in view of Rollero et al. (U.S. 6,506,197). Kensey et al. disclose the invention substantially as stated above including a bar that has a first and second bore. The bores disclosed by Kensey et al. are both in a central region of the bar.

18. However, Rollero et al. discloses that it is old and well known in the art to use suture bars that include 3 holes as seen in Fig. 6a. wherein suture is threaded through each bore (see fig. 6a). Rollero et al. disclose that the three holes provide a way to tie suture to the bar such that the suture bar cannot move along the suture. Incorporating the three hole design in fig. 6a onto the bar of Kensey et al. would allow the bar to be firmly attached to the suture so that it cannot become displaced along the suture during its insertion. Using this configuration, there is a first bore in the central region of the bar and a second bore in the distal region of the bar through which the filament is disposed. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Kensey et al. to include three holes as made obvious by Rollero et al. in order to gain the advantage of being able to thread the filament through either two of the holes in a pulley configuration or through three holes such that the bar can be firmly attached to the suture.

19. **Claims 45-47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Rollero et al. Kim discloses the invention substantially as stated above including the use of either a bore or a eyelet through which a filament is threaded. Kim fails to disclose the use of a bore and an eyelet on the same bar.

20. However, Rollero et al. discloses that it is old and well known in the art to include a plurality of holes in a bar such that a filament can be securely attached to the bar (see fig. 6a

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and 6b). This configuration includes a bore in the central region and in the distal region when the bar is inserted using the delivery sheath of Kim. Therefore, it would be obvious to one of ordinary skill in the art to employ three holes or three eyelets as made obvious by Rollero et al. in the device of Kim so that suture can be securely attached to the bar if desired. This modified device does not include both an eyelet and bore, with one being in the center and one being in the distal region.

21. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an eyelet and a bore, one being in the center and one being in the distal region because applicant has not disclosed that either of these configurations provides an advantage, is used for a particular purpose, or solves a stated problem over the use of either two bores, one in the central region and one in the distal region of the bar, or two eyelets, one in the central region and one in the distal region. One of ordinary skill in the art, furthermore, would have expected modified Kim's device, and applicant's invention, to perform equally well with either two bores or two eyelets, one in the central region and one in the distal region, or the claimed one eyelet and one bore, one in the central region and one in the distal region because both would perform the same function of providing a means of attaching the bar to the filament.

22. Therefore, it would have been prima facie obvious to modify Kim to obtain the invention specified in claims 45-47 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of modified Kim.

23. **Claims 52 and 53** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Rollero et al. Kim discloses the invention substantially as stated above including the use of an eyelet to attach the filament to the bar. Kim fails to disclose the use of a second eyelet

attached to the bar, the first eyelet being in the central region and the second eyelet coupled to the distal region of the bar.

24. However, Rollero et al. disclose that it is old and well known in the art to include connection points between filaments and bars, in this case holes in the bar, wherein there is a central hole and a hole in the proximal and distal regions of the bar. Rollero et al. disclose that the three holes provide a way to tie suture to the bar such that the suture bar cannot move along the suture. Incorporating the three point attachment design in fig. 6a onto the bar of Kim would allow the bar to be firmly attached to the suture so that it cannot become displaced along the suture during its insertion such that pulling on the suture would reorient the bar instead of merely sliding through the holes. Using this configuration with the eyelet of Kim, there is a first eyelet in the central region of the bar and a second eyelet in the distal region of the bar through which the filament is disposed. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Kim to include three eyelets instead of one as made obvious by Rollero et al. in order to gain the advantage of being able to fixedly attach the filament to the bar such that the bar can be reoriented by pulling on the filament.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
9/22/2006


GLENN K. DAWSON
PRIMARY EXAMINER